

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 12, 2012 has been entered.

### ***Response to Arguments***

2. Applicant's arguments filed January 12, 2012 have been fully considered but they are not persuasive. With respect to arguments regarding the Galin reference, Galin also discloses in Col. 1, ll. 49-50 that "[t]he approximately one drop dose can be repeated several times per day **or daily**, as may be necessary" (emphasis added), wherein daily must mean a single dose per day, otherwise the phrase would be redundant with respect to the rest of the sentence. Regarding arguments referring to the affidavit of Dr. Horn, these arguments are also not persuasive as the affidavit was found insufficient to overcome the rejection of claim 33.

### ***Claim Rejections - 35 USC § 102***

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 33-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Galin (U.S. Patent No. 4,443,441).

With respect to **claim 33**: Galin discloses an ophthalmic formulation in aqueous solution for topical administration, comprising: a sterile aqueous carrier (Col. 2, line 11); and a pharmaceutically active compound consisting essentially of phentolamine in a therapeutically effective amount, namely 0.1 - 1 % by weight composition with a water solvent, to contract a pupil of a human patient's eye in dim light so that the pupil is effectively reduced to improve vision in dim light and further to minimize eye redness. Galin also discloses in Col. 1, ll. 49-50 that "[t]he approximately one drop dose can be repeated several times per day **or daily**, as may be necessary." (emphasis added), wherein daily must mean a single dose per day, otherwise the phrase would be redundant with respect to the rest of the sentence.

With respect to **claim 34**: The pharmaceutically active compound disclosed by Galin is present in an amount of 0.1-1% by weight of the ophthalmic solution. As the solvent and major component of the solution is water, and one gram is present in every one cubic centimeter, the active agent is present in an amount of 0.001-0.01 g (1-10 mg) per milligram of solvent or more. Since there are other components in the solution, the weight percent in water of the agent will be greater than the weight percent of agent in solution. This overlaps the claimed range of from about 0.01 milligrams per cubic centimeter of solvent to about 50 milligrams per cubic centimeter of solvent.

With respect to **claim 35**: The sterile aqueous carrier disclosed by Galin comprises purified water, sodium acetate, boric acid and phenylmercuric nitrate and thus it is the examiner's position that the sterile carrier meets the limitation of an ophthalmic artificial tear solution. (Col.

2, lines 3-12)

***Claim Rejections - 35 USC § 103***

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
6. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Galin ('441).

With respect to **claim 36**: It is the examiner's position that since Galin discloses an active agent identical to some disclosed by applicant (e.g. phentolamine), though Galin does not explicitly disclose that the pupil is effectively reduced by 1.0 mm or more, one of ordinary skill in the art can reasonably expect that the solution disclosed by Galin will accomplish this result, rendering claim 36 unpatentable.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/  
Primary Examiner, Art Unit 3761